510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k102428

B. Purpose for Submission:

New device

C. Measurand:

Cannabinoids

D. Type of Test:

Qualitative visually read immunochromatographic assay

E. Applicant:

Hien Helen Nguyen

F. Proprietary and Established Names:

Wunder Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3870, Cannabinoid Test System

2. Classification:

   Class II

3. Product code:

   LDJ

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   A competitive binding immunoassay used for the qualitative determination of Cannabinoids in human urine. The device is visually read and intended for over-the-counter single use. The test has a cutoff of 50 ng/mL of Cannabinoids.

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

3. Special conditions for use statement(s):

   This assay is intended for over-the-counter use

4. Special instrument requirements:

   Not applicable, this is a visually-read single-use device

I. Device Description:

Qualitative immunoassay device intended to detect 9-COOH-11-norΔ^9-THC, a major metabolite of cannabinoids in human urine at a cutoff level of 50 ng/mL. The kit includes a sterile 60 mL urine cup, sterile individually packaged testing strip, package insert, a custody and control form, and a biohazard bag.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   LifeSign Home Drug Test THC

2. Predicate 510(k) number(s):

   k014066

3. Comparison with predicate:

Similarities		
Item	Predicate	Candidate Device
Intended Use	A competitive binding immunoassay used for the qualitative determination of Cannabinoids in human urine.	Same
Product Type	Dipstick	Same
Mechanism of Action	Immunochromatographic lateral flow assay with visual, qualitative screening result	Same
Cutoff Concentration	50 ng/mL	Same
Target User Population	OTC	Same

Differences		
Item	Predicate	Candidate Device
Size	4.25" x 1.2" x 0.2"	3.6" x 0.7" x 0.1"
Physical Design	Plastic casing includes absorbent tip in a "sample well"	Absorbent tip exposed
Storage Temperature	2 - 30ºC	4 - 30ºC

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

The dipstick end of the device, an absorbent nitrocellulose membrane strip, is submerged into a container with the urine specimen and the urine sample migrates towards a region of the dipstick that is coated with a THC-BSA conjugate. A colored anti-THC monoclonal goat anti-mouse antibody-colloid gold conjugate wicking pad is positioned at the end of the dipstick strip, and after the urine sample has migrated through the THC-BSA conjugate area, brining the THC-BSA conjugate with it, if the urine is negative for THC the THC-BSA will react with the anti-THC conjugate to form a color line in the test band region. If the urine sample contains a sufficient concentration of THC then the endogenous THC will saturate the binding sites on the anti-THC antibody conjugates, preventing the THC-BSA from binding and therefore preventing the formation of a color band in the results region of the strip.

A control band coated with monoclonal mouse IgG which binds with the antibody-colloid gold conjugate to ensure that the test is performing properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision of the test was characterized at the sponsor's facility by two operators. Samples were commercial urine (Biorad Liquicheck Urine Toxicology Control; with THC concentrations ranging from 0 ng/mL to 140 ng/mL) that were mixed to obtain the target concentrations. Testing was performed using three different device lot numbers. Three lots (aliquots) of total 27 samples were prepared which included drug-free urine, drug-free urine spiked to 75% below cutoff, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff, 50% above cutoff, 75%	Drug-free urine	-75% cutoff	-50% cutoff	-25% cutoff	Cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff

above cutoff and 100% above cutoff. Each three lots of 27 samples were assayed once a day for 20 days, yielding a total of 60 runs per sample concentration. Results are presented below.									
Concentration (ng/mL)	0	12.5	25	37.5	50	62.5	75	87.5	100
THC Negative	60	60	60	60	4	0	0	0	0
THC Positive	0	0	0	0	56	60	60	60	60

A separate cutoff characterization study was performed to assess the 50 ng/mL cutoff concentration of the device. 20 devices from 3 lots were tested at each of 8 sample concentrations made from spiking commercial THC into drug-free urine. The results are below.

	Drug-free urine	-75% cutoff	-50% cutoff	-25% cutoff	Cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Concentration (ng/mL)	0	12.5	25	37.5	50	62.5	75	87.5	100
Lot 1 THC (+/-)	0/20	0/20	0/20	0/20	18/2	20/0	20/0	20/0	20/0
Lot 2 THC (+/-)	0/20	0/20	0/20	0/20	19/1	20/0	20/0	20/0	20/0
Lot 3 THC (+/-)	0/20	0/20	0/20	0/20	19/1	20/0	20/0	20/0	20/0

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

All materials are traceable to the commercial suppliers from which they are purchased.

An accelerated study was performed to determine the shelf life of the candidate device. The study was designed based on the bracket table technique where the *Wunder Test*™ was stressed at 50ºC for 60 days to predict stability for 2 years. The protocol and acceptance criteria was reviewed and found to be acceptable, yielding a stable shelf life at 4 - 30ºC of 2 years.

Real-time stability study protocols and acceptance criteria were reviewed and found

to be acceptable. These studies are ongoing.

d. Detection limit:

Sensitivity of a qualitative assay may be characterized by validating performance around the claimed cutoff concentration of the assay, and demonstrating the lowest concentration of drug that is capable of consistently producing a positive result. This information appears in the precision section (please see above).

e. Analytical specificity:

Twenty three compounds and nine biologic substances were tested for interference by testing various amounts of each compound when added to urine with at 37.5 ng/mL THC (-25% cutoff) and at 65 ng/mL (+25% cutoff). Five samples were tested for each compound by a single operator at the sponsor's facility. All test results were negative.

Several structurally related compounds were tested for cross reactivity. Various amounts of each compound (serial dilutions from an original cross-reactant concentration of 100 µg/mL) were tested in drug-free control urine and cross-reactivity was determined by when the test result changed from positive to negative. Results are expressed as cross-reactant concentration equivalent to analyte cutoff, and are shown below.

Compound	Response equivalent to cutoff in ng/mL
Δ^9-Tetrahydrocannabinol	15,000
Cannabinol	20,000
Δ^8-Tetrahydrocannabinol	25,000
11-nor- Δ^9-Tetrahydrocannabinol carboxylic acid	50
Cannabidiol	100,000

Several structurally unrelated compounds were tested for interference:

Compound Concentration (100 µg/mL)	-25% of cutoff (37.5 ng/mL) negative/positive	+25% of cutoff (62.5 ng/mL) negative/positive
Acetaminophen	NEG	POS
Acetylsalicylic acid	NEG	POS
Ampicillin	NEG	POS
Ethanol	NEG	POS
Lidocaine	NEG	POS
Aspirin	NEG	POS
Atropine	NEG	POS

Benzoic acid	NEG	POS
Oxalic acid	NEG	POS
Caffeine	NEG	POS
Methanol	NEG	POS
Pencicillin-G	NEG	POS
Ranitidine	NEG	POS
Salicylic acid	NEG	POS
Drug compounds from Biorad Liquitox™ Urine Toxicology Control	-25% of cutoff (37.5 ng/mL) negative/positive	+25% of cutoff (62.5 ng/mL) negative/positive
d-Amphetamine	NEG	POS
Secobarbital	NEG	POS
Nordiazepam	NEG	POS
Benzoylecgonine	NEG	POS
Lysergic acid	NEG	POS
Methadone	NEG	POS
Methaqualone	NEG	POS
Morphine	NEG	POS
Phencyclidine	NEG	POS
Propoxyphene	NEG	POS
Nortriptyline	NEG	POS
Biologic substances	-25% of cutoff (37.5 ng/mL) negative/positive	+25% of cutoff (62.5 ng/mL) negative/positive
Albumin	NEG	POS
Bilirubin	NEG	POS
Creatine	NEG	POS
Hemoglobin	NEG	POS
Glucose	NEG	POS
Vitamin (L-Ascorbic Acid)	NEG	POS
Uric acid	NEG	POS
Urine pH	NEG	POS
3.0	NEG	POS
4.0	NEG	POS
5.0	NEG	POS
6.0	NEG	POS
7.0	NEG	POS
8.0	NEG	POS
9.0	NEG	POS
Urine specific gravity (g/mL)		
1.010	NEG	POS
1.020	NEG	POS
1.030	NEG	POS

f. Assay cut-off:

The cut-off characterization study results can be found in the precision section of this summary.

2. Comparison studies:

a. Method comparison with predicate device:

In order to characterize performance of the *Wunder Test*™ assay compared with GC/MS testing, 80 clinical samples were purchased from a laboratory and analyzed with each assay. Samples were unaltered and were selected with the intent to obtain adequate distribution of the targeted drug around the claimed cutoff concentration. The samples were categorized based upon the GC/MS result concentration of THC. Results were obtained by the sponsor's in-house laboratory and by an outside GC/MS laboratory, and are presented below.

THC Metabolite	Test Positive	Test Negative
True Negative (drug-free urine)	0	20
Low Negative (<50% cutoff)	0	20
Near Cutoff Negative (between -50% + cutoff)	0	20
Near Cutoff Positive (between cutoff + 50%)	17	3
High Positive (>50% cutoff)	20	0

Discordant Results #1

Cutoff Value (ng/mL)	*Wunder Test*™ (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)
50	Negative	55.45
50	Negative	50.00
50	Negative	50.76

In addition, 44 samples (40 from the positive category and 4 from the negative category above) were sent to a separate certified laboratory for confirmatory GC/MS testing, and results are presented below.

THC Metabolite	Near Cutoff Negative (between -50% & cutoff)	Near Cutoff Positive (between cutoff & + 50%)	High Positive (>50% cutoff)
Positive	1	17	20
Negative	3	3	0

Discordant Results #2

Cutoff	*Wunder Test*™	Drug/Metabolite

Value (ng/mL)	(POS/NEG)	GC/MS value (ng/mL)
50	Positive	48
50	Negative	44 *
50	Negative	48 *
50	Negative	47 *

*These samples tested positive at the first GC/MS Laboratory confirmation but negative and this secondary GC/MS Laboratory confirmation testing; therefore although they are not discordant results as shown in the above Discordant Results #2 table, they were categorized as Positive samples from the first GC/MS Laboratory results (the 3 discordant results from Discordant Results #1) and are therefore listed here with the discordant results as well as above.

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable. Clinical studies are not typically submitted for this device type and matrix.

b. Clinical specificity:

Not applicable. Clinical studies are not typically submitted for this device type and matrix.

c. Other clinical supportive data (when a. and b. are not applicable):

A consumer study was performed with 192 lay-users. Urine samples were purchased at specific drug concentrations, or spiked to desired concentrations and distributed to volunteers at one of three locations. Volunteers were of various age, race, sex and educational backgrounds, and none had ever before used a drug test. Volunteers tested the urine samples using the *Wunder Test™*. Volunteers were provided with the instructional materials available in the device packaging. Testing was conducted at three separate locations. Combined results are divided into concentration categories based upon the GC/MS result of each sample, and are presented below.

THC (ng/mL) category by GC/MS	Drug-free Urine (0)	75% Below Cutoff (<12.5)	50% Below Cutoff (25)	25% Below Cutoff (37.5)	25% Above Cutoff (67.5)	50% Above Cutoff (75)	100% Above Cutoff (>100)

Wunder Test™ Positive/Negative	0/20	0 / 30	0 / 35	4 / 30	34 / 0	32 / 0	27 / 0

A post-test survey of volunteers showed that 100% thought that the test was easy to run, easy to read, and that result line shading does not matter (a question specifically addressed in the device instructions). A Flesh-Kincaid reading analysis resulted in a reading grade level of 7.8.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.